REMARKS

Claim 1 has been amended to add a period at the end of the claim in order to overcome the Examiner's objection to claim 1. Upon entry of this amendment, claims 1-31 will remain pending in the present application.

I. The Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-3 and 4-31 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is traversed and reconsideration is requested for the reasons which follow.

Claim1 and dependent claims 2-3 and 8-31 were rejected on the basis that these claims recite the limitation "elevated temperature." The Examiner takes the position that because "elevated" is a relative term it renders the claim indefinite on the basis that it is impossible to determine the temperature range intended to be claimed.

The applicant agrees that "elevated" is a relative term. However, it is clear from the specification and the common general knowledge of a skilled person what is meant by "elevated temperature" in the context of claims 1-3 and 4-31 of the present application. More particularly, a skilled person would immediately understand that a reaction mixture is provided to the high shear apparatus at a particular temperature, which may be ambient or room temperature, for example, though it need not be. The claim then requires that the high shear treatment be conducted at elevated temperature. This clearly means that the temperature of the reaction mixture at some point during the high shear treatment will be higher than the temperature of the reaction mixture as provided to the high shear treatment. Accordingly, in the context of the present application, there is a clear baseline for determining what is an elevated temperature and it would be a routine matter for a skilled person to determine if the temperature of the reaction mixture during the high shear treatment is higher that the temperature of the reaction mixture as provided to the high shear treatment.

Moreover, the applicant would like to draw the Examiner's attention to the fact that a search of the USPTO database revealed that 14,373 U.S. patents issued since 1976 employ the term "elevated temperature" in one or more claims providing a further

indication that this is a term that is well-defined in the art an can be interpreted with a reasonable degree of certainty by a skilled person.

Accordingly, favorable consideration and withdrawal of the rejection of claims 1-3 and 8-31 on this basis is requested.

Claims 4-7 have been rejected on the basis that the term, "at least about" is a relative term that renders these claims indefinite. This rejection is traversed and reconsideration is requested for the reasons which follow.

MPEP §2173.02 states that, "When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness." Thus, the Examiner must bear in mind that absolute certainty is not required, but rather only reasonable certainty.

MPEP §2173.05(b) further provides as follows:

> **2173.05(b) Relative Terminology [R-5]**
> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

There are two important points in this section. First, terms of degree, such as "at least about" do not automatically render the claim indefinite. Thus, the Examiner must justify why, under the present circumstances, the term, "at least about" renders the claim indefinite.

Second, whether "at least about" is acceptable depends on whether one of ordinary skill in the art would understand what is claimed in light of the specification. In this regard, the Examiner took the position that, "...the specification does not provide a standard for ascertaining the requisite degree." The applicant disagrees with this conclusion.

For example, the specification at page 8, line 4 indicates that the reaction mixture generally will heat to "at least about 40°C." Then, at page 8, line 12, the specification

indicates that a preferred temperature range is "about 50 to 110 °C." From this, a skilled person can readily infer that "at least about 40°C" must be different than "about 50°C" or the specification would not have mentioned "about 50°C" as a preferred embodiment. Thus, a skilled person could draw the conclusion that "about" means ± 5°C since otherwise "about 40°C" would overlap with "about 50°C." Accordingly, guidance in the specification for interpretation of the term, "at least about" contrary to the Examiner's assertion and thus this rejection should be withdrawn.

The applicant would also like to call to the Examiner's attention to the fact that 68,946 U.S. patents issued since 1976 employ the phrase "at least about" in one or more claims thereby giving a further indication that in numerous circumstances this terminology is definite.

Favorable consideration and withdrawal of the rejection under 35 U.S.C. §112 is requested.

II. The Rejections Under 35 U.S.C. §103(a)

Claims 1-7, 20, 22-24, 26 and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent no. 6,228,232 B1 (Hanna et al.), in view of WO 01/02441 A1 (Schaible et al.) and U.S. Patent no. 6,392,034 B1 (Trusovs et al.). This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

The present invention, as claimed in claim 1, relate to a process for the production of microcrystalline cellulose. In the process, a reaction mixture comprising a cellulose material, an active oxygen compound and water, is subjected to a high shear treatment at elevated temperature for a time effective to depolymerize the cellulose material. The present invention provides an efficient, one-step process for the production of microcrystalline cellulose.

The Examiner admits that the primary reference to Hanna et al. does not disclose a process for producing microcrystalline cellulose using an active oxygen compound. Rather, Hanna et al. produces microcrystalline cellulose by extrusion of cellulose with an acid, wherein the temperature of the extruder barrel may be from 80-200°C. When

wood cellulose is employed as the starting material a level-off degree of polymerization of the obtained microcrystalline cellulose may be 220.

Schaible et al. teaches a process for the production of microcrystalline cellulose by hydrolyzing pulp with active oxygen. The method simultaneously hydrolyzes and bleaches the starting material to obtain a microcrystalline cellulose product. (See page 2, lines 20-24 of Schaible et al.).

Trusovs et al. teaches a method of producing microcrystalline cellulose by first treating cellulose with an alkaline solution at a temperature between 20 and 100 °C to provide an alkaline suspension and then adding hydrogen peroxide or another type of peroxide solution to reduce the viscosity of the alkaline suspension and thereby produce microcrystalline cellulose.

The Examiner takes the position that it would have been obvious to use the reactive extrusion process of Hanna et al. with hydrogen peroxide to produce microcrystalline cellulose (see page 5, lines 4-6 of the Office Action). The applicant disagrees with this conclusion for several reasons.

Hanna et al. employs acid hydrolysis to de-polymerize wood pulp by cleaving the cellulose chains in the amorphous regions but leaving crystallites hydrogen bonded to each other. This is not the chemical equivalent of treatment with an active oxygen compound as in the present invention. More specifically, the present specification teaches that treatment with an active oxygen compound provides some different effects on the cellulose that appear to be independent of acid hydrolysis. See e.g. page 9, lines 10-16 of the application. Also, Trusovs et al., suggests that treatment with peroxide causes some oxidation of the cellulose to occur. See column 2, lines 49-53 of Trusovs et al.

A skilled person would therefore not substitute an active oxygen treatment for an acid hydrolysis step of Hanna et al. for the reasons suggested by the Examiner since the active oxygen treatment has the additional effect of oxidizing the cellulose material. There is no mention of oxidation occurring in the acid hydrolysis step of Hanna et al. Thus, the oxidation would likely result in a significant chemical change in the cellulose material that is not contemplated by Hanna et al. As a result, the skilled person would expect that the properties of the cellulose material produced by the process of Hanna et

al. would be materially changed if the active oxygen treatment were substituted for the acid hydrolysis reaction of Hanna et al., due to the additional oxidation reaction caused by active oxygen treatment. This would lead a skilled person to conclude that the active oxygen treatment should not be substituted for, or added to, the acid hydrolysis step of Hanna et al. since the effect of the additional oxidation reaction on the properties of the resultant microcrystalline cellulose of Hanna et al. for use to make tablets (see e.g. col. 6, lines 15-22 of Hanna et al.), would be unknown and unpredictable in view of the disclosure of Hanna et al.

The Examiner relies on the statement that the extruder method has a shorter reaction time than conventional methods for the purpose of alleging an expectation of success by a skilled person. However, Hanna et al. does not disclose the reaction time required for the extruder method. Neither Schaible et al. nor Trusovs et al. relate to the conventional methods referred to by Hanna et al. Thus, the skilled person cannot actually determine from the cited references whether use of the extruder method would produce a shorter reaction time than is needed in Schaible et al. or Trusovs et al.

The Examiner also alleges that it would have been obvious to employ hydrogen peroxide in the extruder method of Hanna et al. since no separate bleaching step would be required. However, in the method of Hanna et al. a bleaching step is not always necessary, depending on the quality of the starting cellulose material that is employed. See e.g. col. 4, lines 49-54 of Hanna et al.

In addition, although some bleaching occurs in the processes of Schaible et al. and Trusovs et al. it is not clear that the effectiveness of this bleaching is sufficient to obviate the need for a separate bleaching step as the Examiner alleges. For example, the amount of bleaching required depends, to a large extent, on the starting cellulose material. See e.g. col. 4, lines 49-54 of Hanna et al. Thus, for example, in Example 1 of Schaible et al., an unbleached cellulose obtained by acid hydrolysis had a lightness value of 70.84. The bleached cellulose obtained using hydrogen peroxide bleaching in Example 11 of Schaible et al. had a lightness value of only 69.2. Clearly, a further bleaching step may be required in this instance. Accordingly, a skilled person would not conclude from the teachings of the cited references that inclusion of a peroxide in the extruder method of Hanna et al. would necessarily eliminate the need for a further bleaching step since the

need for a further bleaching step will depend on a number of factors including at least: (1) the starting material employed (see e.g. col. 4, lines 49-54 of Hanna et al., (2) the amount of hydrogen peroxide employed, and (3) the specifications for the desired final product.

Finally, with respect to Trusovs et al., this document is concerned with avoiding the use of an acid hydrolysis method. See e.g. col. 1, lines 34-38 and col. 2, lines 10-15 of Trusovs et al. In addition, another object of Trusovs et al. is to provide a method for producing MCC which does not involve high temperature or high pressure applications (See col. 2, lines 22-24 and 38-41 of Trusovs et al.). Thus, a skilled person would not combine Trusovs et al. with Hanna et al. since Hanna et al. employs both high pressures (extruder) and high temperatures of 200-230°C (see e.g. the only example of Hanna et al. at col. 6, lines 59-60). A skilled person would not combine Trusovs et al. with either Hanna et al. or Schaible et al. since both employ acid hydrolysis methods which Trusovs et al. is trying to avoid. Thus, Trusovs et al. should be withdrawn from the rejection as non-analogous art.

With respect to product claims 22-24 and 26, the skilled person would expect that these products would be substantially different from the products produced by the method of Hanna et al. because the chemical reactions that occur when peroxide is present during the acid hydrolysis step are different than acid hydrolysis reactions, as discussed above.

Accordingly, for at least these reasons, withdrawal of the rejection of claims 1-7, 20, 22-24, 26 and 28 under 35 U.S.C. §103(a) is requested.

Claims 18-21, 25-27 and 29-31 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent no. 6,228,232 B1 (Hanna et al.), in view of WO 01/02441 A1 (Schaible et al.), U.S. Patent no. 6,392,034 B1 (Trusovs et al.) and U.S. Patent no. 5,192,569 (McGinley et al.). This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

McGinley et al. does not cure the defects of the primary references discussed above. Accordingly the same reasons as applied to the rejection of claims 1-7, 20, 22-24, 26 and 28 under 35 U.S.C. §103(a), also apply to the rejection of claims 18-21, 25-27 and 29-31 since each of these claims depends from claim 1. Withdrawal of the rejection is requested.

Favorable consideration and issuance of a Notice of Allowance is requested.

Respectfully submitted,

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